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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,188	02/12/2004	Peter James Jenkins	08505.0020	3089

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EXAMINER	
PESELEV, ELLI	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 09/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/776,188	JENKINS ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-24,26-29 and 39-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-24, 26-29 and 39-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Applicant's arguments filed August 24, 2006 have been considered but are moot in view of the new ground(s) of rejection.

Upon further consideration, the Final Action of March 6, 2006 and the allowance of claims 8-24, 26-29 and 39-41 is hereby withdrawn in order to introduce a new ground of rejection.

Claims 8, 11-24, 26-29 and 39-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of diabetes with Gibberellin A3 and Gibberellin A3 and A4/A7 mixture, does not reasonably provide enablement for the treatment of diabetes with Gibberellins of Formula (1). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The nature of the invention.

Drug discovery is one of the most labor intensive and expensive types of inventions; it can cost over $500 million to bring a single new drug to market.

(B) The state of the prior art.

The art is unaware of successful treatment of diabetes with chemically analogous compounds.

(C) The predictability or lack thereof in the art.

"In applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims" (see MPEP 2164.03). In the present case, the specification presents data showing the effect on blood glucose levels of Gibberellin A3. Based on the evidence of activity limited to Gibberellin A3, it cannot be predicted what other Gibberellins having diverse structural formulas encompassed by the present claims will have similar effect on blood glucose levels as Gibberellin A3.

(D) The amount of direction or guidance present.

The specification discloses a single specific compound and said compound with A4/A7 mixture which has a blood sugar lowering activity. However, this guidance is not commensurate with the full scope of the claims.

(E) Breadth of the claims.

The claims encompass an immense number of species having significant differences in structural formulas. For example, a compound of Formula (1) wherein R1, R2, R3, R4, R5, R6, R7, R8, R9, R10 and R11 are hydrogens is significantly different structurally from the compound of Formula (I) wherein R1 , R2, R3, R5, R7, R8 and R10 are glycosylic ether groups, R4 is C20 alkyl, R6 and R10 are hydroxy groups. R8 is

(F) The quantity of experimentation needed.

Because there is no way to predict a priori which compounds will be active from the specification or chemical structures alone, an extraordinary amount of trial and error experimentation is required to identify the active compounds.

Claims 8-16 and 39-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of diabetes, does not reasonably provide enablement for the treatment of complications and associated conditions of diabetes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or the full scope of the claimed invention.

(A) The breadth of the claims.

On page 6 of the specification, lines 20-29, the complications of diabetes and its associated conditions are defined as including obesity, micro- and macro-vascular diseases, nephropathy, neuropathy, eye diseases, diabetic ulcerations and the like.

(B) The amount of direction or guidance present.

The specification fails to provide any guidance as to effectiveness of the claimed methods in treating compications and associated conditions of diabetes.

(C) The present or absence of working examples.

The working example presented on pages 22-23 of the specification, shows that following administration of Gibberellin A3, after 30 days there was observed an increase in body weight. Therefore, there is a good reason to doubt that Gibbellins are effective in treating obesity as encompassed by the present claims.

(D) The quantity of experimentation needed.

Because there is no way to predict for which complications and associated conditions the claimed methods would be effective, an extraordinary amount of trial and error experimentation is required to identify the specific conditions for the treatment of which the claimed methods will be useful.

It has been noted that Applicants previously argued that one of ordinary skill in the art would have known that diabetes and its complications and associated conditions arise from abnormal serum glucose levels. However, there is no evidence that lowering blood sugar in a patient will result in the treatment of such diseases as obesity, micro and macro vascular disease, nephropathy, neuoropathy and eye diseases, once those diseases once those diseases are established.

Claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11-15 are directed to the treatment of Type I and Type II diabetes. However, there is no known patient having Type I and Type II diabetes. Such terminology as "Type I or Type II diabetes" can be used to overcome the rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev

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